

Serial No.: 10/701,038

Atty.Dkt. No.: CLFR:235US

REMARKS**I. Status of the Application**

Claims 1-34 were pending. Claims 1-5, 7-14 and 16-26 are canceled. Claim 6, 30, 33 and 34 are amended to further clarify the claims and to address the new grounds of rejection presented in the final Office Action. Claims 6, 15, and 27-34 are currently pending. Support for the amendments can be found at least on page 13 and 14. The pending claims comply with the requirements of the final Office Action and are in condition for allowance, or alternatively are in better form for consideration on appeal.

II. New Claim Objections

Claim 30 is objected to as being an improper dependent claim due to claim 30 failing to further limit claim 6. Claims 31-34 are objected to as being duplicates of claims 15, 27, 28, and 29, respectively. In light of the current amendments to claim 30 this objection is moot. Applicants respectfully request the withdrawal of the objection.

III. Rejection of Claims under 35 U.S.C. §112, first paragraph

Claims 6, 15, and 27-34 are rejected as failing to comply with written description requirement because the claims allegedly contain subject matter not described in the specification in such way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Action alleges that (A) no baseline sequence is provided for the *E. Canis* immunoreactive surface protein p153 gene and (B) none of the claimed proteins meet the written description requirement. The Action cites *Fiers v. Revel*, 984 F.2d 1164, 25 USPQ2d 1601, and *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 18 USPQ2d 1016, in support of the rejection. Applicants respectfully traverse.

25625853.1

Serial No.: 10/701,038

Atty.Dkt. No.: CLFR:235US

Applicants currently claim isolated and purified polypeptides of *Ehrlichia canis* immunoreactive surface protein p153 having an amino acid sequence shown in SEQ ID NO:2, having amino acids 361 to 663 of Genbank accession number AF252298 (GI:37528969), having amino acids 651 to 983 of Genbank accession number AF252298 (GI:37528969); and having amino acids 981 to 1406 of Genbank accession number AF252298 (GI:37528969). Genbank accession number AF252298 is disclosed on page 14 of the specification and a description of the peptide sequences are provided at least on page 13 of the specification. Based on Applicants disclosure of the full length nucleic acid sequence and polypeptide sequence of *E. canis* immunoreactive surface protein p153 as revised Genbank accession number AF252298 one of skill in the art would reasonably conclude that Applicants possessed the subject matter claimed. The full nucleic acid and polypeptide sequence are disclosed in the application.

Applicants clarify the claims by claiming the polypeptides directly as amino acid sequences instead of describing the polypeptides using the encoding DNA sequence. Applicants' specification provides written description for all amino acid sequences by reference to Genbank accession number AF252298 (*see* Genbank record, Exhibit A) as well as additional description of the use and relationship of the submission as it relates to the claimed invention. Page 14, line 9 to line 14 of the specification discloses the Genbank accession number (AF252298) and indicates the submission of the revised sequence as initially given Genbank accession number AY156950. However, the AF252298 record was updated to include the revised sequence instead of establishing the new accession number. The AF252298 record specifically states that the revised sequence (A) was submitted on September 30, 2002 and (B) replaced the earlier version of accession number AF252298 (gi:12658962). A skilled artisan had access to the chemical structure of the nucleic acids and the proteins encompassed by the current

25625853.1

Serial No.: 10/701,038

Atty.Dkt. No.: CLFR:235US

invention by virtue of the disclosure of the Genbank accession number in the specification as filed.

Furthermore, the present invention is distinct from the facts underlying the *Fiers v. Revel* and *Amgen v Chugai* cases, which were cited in support of the rejection. In these cases the conception date of a nucleic acid sequence was the date the actual DNA sequence was known. The cases hold that the description of methods for isolating a fragment of DNA and methods for isolating a corresponding mRNA is insufficient description of a nucleic acid sequence or an amino acid sequence encoded by the nucleic acid. In contrast, the present application does not rely on methods of isolation for identifying or describing the nucleic acid or polypeptide sequences, it discloses the sequences in the application. Therefore, the present application provides more than the mere description of the methods for isolating a DNA sequence. Thus, the holdings in *Fiers v. Revel* and *Amgen v Chugai* are not relevant to the present application. Applicants were in possession of the invention and the Genbank accession number describes the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.

Applicants note that none of the rejections speak to the insufficiency of Genbank accession number AF252298 and no notification of informalities regarding the sequence listing was conveyed to the Applicants during prosecution. Applicants respectfully request withdrawal of the rejection.

IV. Rejection of Claims under 35 U.S.C. §112, second paragraph

Claims 6, 15, and 27-34 are rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject that applicants regard as their invention. The claims are allegedly vague and indefinite for the following

25625853.1

Serial No.: 10/701,038

Atty.Dkt. No.: CLFR:235US

reasons: (A) claim 6 for not referencing a baseline sequence, and (B) claim 33 and 34 for lacking antecedent basis for "surface."

In light of the present claims the rejection is moot. Claim 6 now references Genbank accession number AF252298 and claims 33 and 34 now depend from claim 32, providing antecedent basis for surface. Applicants request the withdrawal of the rejections.

CONCLUSION

Applicants believe that the foregoing remarks fully respond to all outstanding matters for this application. Applicants respectfully request that the rejections of all claims be withdrawn so they may pass to issuance. Alternatively, Applicants request the entrance of the amendments to better prepare the claims for appeal.

The Examiner is invited to contact the undersigned patent agent at 512-536-3167 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



Charles P. Landrum, Ph.D.
Reg. No. 46,855
Agent for Applicants

FULBRIGHT & JAWORSKI L.L.P.
600 Congress Avenue, Suite 2400
Austin, Texas 78701
512-536-3167



Date: March 9, 2006

Serial No.: 10/701,038

Atty.Dkt. No.: CLFR:235US

EXHIBIT A

25625853.1

[PubMed](#)
[Nucleotide](#)
[Protein](#)
[Genome](#)
[Structure](#)
[PMC](#)
[Taxonomy](#)
[OMIM](#)
[Books](#)

Search for

[Limits](#)
[Preview/Index](#)
[History](#)
[Clipboard](#)
[Details](#)

Display Show Send to

Range: from to
☐ Reverse complemented strand
 Features: ☐ SNP ☒ CDD ☐

☐ 1: [AF252298](#). Reports *Ehrlichia canis* 2...[gi:37528969]

[Links](#)

[Comment](#) [Features](#) [Sequence](#)

LOCUS AF252298 4266 bp DNA linear BCT 06-OCT-2003
 DEFINITION *Ehrlichia canis* 200 kDa immunoreactive glycoprotein gene, complete cds.
 ACCESSION AF252298
 VERSION AF252298.2 GI:37528969
 KEYWORDS
 SOURCE *Ehrlichia canis*
 ORGANISM *Ehrlichia canis*
 Bacteria; Proteobacteria; Alphaproteobacteria; Rickettsiales; Anaplasmataceae; Ehrlichia.
 REFERENCE 1 (bases 1 to 4266)
 AUTHORS McBride, J.W., Corstvet, R.E., Breitschwerdt, E.B. and Walker, D.H.
 TITLE Immunodiagnosis of *Ehrlichia canis* infection with recombinant proteins
 JOURNAL J. Clin. Microbiol. 39 (1), 315-322 (2001)
 PUBMED 11136790
 REFERENCE 2 (bases 1 to 4266)
 AUTHORS McBride, J.W., Comer, J.E. and Walker, D.H.
 TITLE Novel Immunoreactive Glycoprotein Orthologs of *Ehrlichia* spp
 JOURNAL Ann. N. Y. Acad. Sci. (2003) In press
 REFERENCE 3 (bases 1 to 4266)
 AUTHORS McBride, J.W. and Walker, D.H.
 TITLE Direct Submission
 JOURNAL Submitted (04-APR-2000) Pathology, University of Texas Medical Branch, 301 University Blvd., Galveston, TX 77555, USA
 REFERENCE 4 (bases 1 to 4266)
 AUTHORS McBride, J.W. and Walker, D.H.
 TITLE Direct Submission
 JOURNAL Submitted (30-SEP-2002) Pathology, University of Texas Medical Branch, 301 University Blvd., Galveston, TX 77555, USA
 COMMENT On Oct 6, 2003 this sequence version replaced gi:12658962.
 FEATURES
 source Location/Qualifiers
 1..4266
 /organism="Ehrlichia canis"
 /mol_type="genomic DNA"
 /db_xref="taxon:944"
 CDS 1..4266
 /note="gp200"
 /codon_start=1
 /transl_table=11
 /product="200 kDa immunoreactive glycoprotein"
 /protein_id="AAK01145.2"
 /db_xref="GI:37528970"

/translation="MSDPKQGDPEQNQTNPSSGDIQDQSQDQEQDQQQCAVGGAVGN
SPIERERVAAPESSELYTVIIPKGRKTAAPILERKSPTPEPKVEDDEDLPPTLPDPTF
SGEGYDDVGVSMPTVSRGIYQPPIVQDSNLYSSIGGVPEAQYDAAARAGGPRKFLYG
PYTFSNGQEIMDFEFDTPWPDVRNAV LGNKEIKEEWLTTSGPVRDIADRI VASKGDL S
EDQVEHILDIIFMNESEIABGISNPLHADVDNPNVKGAKNVM TLMHLVYACDVPRI V
KALGEVENDEGDLGANAYNVLDSEGNLPLHHA AKNCTGDKLKLCKMEKTKTDFIDTANF
ANQSPLHIITQKPDSCVLDIEEPTSRNLD FGLVDGDKNPLHHA VEHLPPVILKGVM D
HVKNSSEFQDLVNDPDYFGNTIAHYAVKNKNADLTLE NMLKASGADLNVRNVVGRAP I
HVASSNGKANAVSGLVSCGIDVNSQDVNGDTP LHI AVEGGSMETVLAVLNQRGADVSV
QNN DGVT PMLSAAKYGDIGV I KALGSAKPNIKG EDTVAKSLLM EDYKGF TPLHFVAGG
GSRDTPRVVRKNYEKCHDLATIRAALMQDRSGGELVNLGDFESENILGSPNAKFLQHI
QSANFGFSFARRGI VSSNHNVMKDILNFVGDSLHLP SERGYNAMQVAALFGDKEAVKM
LAKSAKPSDLNPKTSATPTPLNLACLRC DNEVVRGLVQGHGIDINQRMGSDKNTVLHY
AISKGDSFLVQKILAHTGVDVNCENNLGQTPLHLAVEGGDPKIVSSLLKAGAVVNRLD
DNGRSVLSSAIVPGRKEKGV LGIVNKL LDRGADINLDGDHNLIFDQCLRGGYNNVLDK
LIQQGVEVNRNSEIRPMVYAAISGNEHA I KSLANAGGDVNEVVNPNSSRHSNPLIMV
AVADGNAGLLKTLVSEGCDVGKSGKGNTALHYAVSHSDKEFGNKA I KILISRNSVGT
NRDILTQKNNAGDTP LHEALKSGNINSVQNILSAVHPRYAKEILTARDKEGYTPMHYT
VGVNNVDVGRSILESMLS KGVNNLGEIVGAQDSNFRTP LHA A I KISDYRAADMIIGSL
SKTELSKLSQLTDINGDTP LHLSCQSGNVEMTQFFLGGLDKREL PKTLKIANKNGDTP
LHDAIRNDDIKSAKMMIRNCNKEELANVLKCKDSFGNTVLHTIADQVIANPESKKDL D
GLMNLAVKRLKNQDLKDLVNTRNNSDDTVAHCALLSDMKYAQKILKSCNHD TLVRGNS
NNQSLSECIRDDSKYKKGCI FSKSLFSKLKKLEARAASAYEELSSISSGSDVSSVST
NSTEVS AVPEVARSSGAVSFKHVQETGVDTSGPSDIESLERLSDTSLGSNDFDQRMAD
LDQEIANIVSGLPEVTQVAVSQQQAASPSGQAAGVQQKEMQR"

ORIGIN

1	atgtcagatc	caaaacaagg	tgatccagaa	caaaatcaaa	ctaaccctag	tggtgatatt
61	caggatcaaa	gtcagcaaga	tcaacaggaa	caagatcagc	agcagggagc	agttggtggt
121	gctggttggt	atagtcctat	tgaagagag	agagtagctg	ctcctgagag	tgaagattta
181	tatactgtga	ttatacctaa	gggtaaaaga	actgctgctc	caatttttga	aagaaaagtct
241	cctactcctg	aaccgaaagt	agaagatgat	gaagatttac	ctcctacatt	accgccaaga
301	acatttttcag	gagaaggata	tgatgacgtt	ggagttagta	tgctactgt	tagtcgtggc
361	atataccaac	ctcccatagt	tcaagatagt	aatctatatt	caagtattgg	tgccgtacca
421	caagaagcac	aatatgatgc	agcagctcgg	gctggtgggc	caagaaagt	ttgtatggg
481	ccatatacat	tcagtaatgg	tcaggaaatt	atggactttg	aatttgatgc	tccttgcca
541	gatgttagga	atgcagtttt	aggtaataaa	gagataaaa	aagagtgggt	aactacttct
601	gggccagtac	gtgatattgc	tgataggata	gttgcttcta	aaggtgattt	gtctgaggat
661	caagtagaag	aaatccttga	tatttatatt	atgaatgaat	cagaaatcgc	tgaaggtatt
721	tctaateccat	tacatgctga	tggtgataat	aatcctgtta	aaggtgctaa	gaatgtgatg
781	acattgatgc	atctagttta	tgcagtgtat	gttgatccac	gtatagtaaa	agctttagga
841	gaggtggaaa	atgatgaagg	tgatttagga	gctaattgct	ataatgtttt	agatagttag
901	ggtaatcttc	ctttacatca	tgctgcaaa	aattgtacag	gggataagtt	aaagctttgt
961	atggagaaaa	caaagactga	ttttattgat	actgcaaatt	ttgcgaatca	atcccttta
1021	catattatta	cacagaagcc	agattgttct	gtattagata	ttgaagagtt	tacaagccgt
1081	aatttagatt	ttggacttgt	agatggagat	ggtaaaaaatc	ctttacatca	tgctgttgaa
1141	catttgccac	ctgttatact	taagggcgta	atggaccatg	taaaaaatag	tagtgagttt
1201	caagatttag	taaagatgcc	tgattatttt	ggaaataacta	tagctcatta	tgagttaaag
1261	aataaaaatg	ctgatttaac	attgtttaac	atgctgaaa	cttcaggagc	tgatttaaat
1321	gttaggaatg	tagttggtcg	agctccaata	catgttgctt	cttctaattg	taaggctaatt
1381	gcagtttctg	gacttgatc	atgttggtatt	gacgttaatt	ctcaagatgt	gaatggagat
1441	acaccacttc	atattgctgt	tgaaggcggt	agtatggaga	cggtattagc	agtgttaaat
1501	cagagaggtg	ctgatgttag	tgtccagaat	aacgatggag	ttacacctat	gcttagtgct
1561	gctaaatatg	gagatatagg	tgtaataaaa	gctttagggt	cagctaaacc	aaatatataa
1621	ggtgaagaca	ctgttgctaa	atcattgctg	atggaggatt	acaaagggtt	tacacccttg
1681	cattttgtag	ctggtggtgg	tagcagagat	acattccgtg	tcgtaagaaa	aaattatgaa
1741	aaatgtcatg	acttagctac	tattagggca	gctttaatgc	aagatagaag	cggtggtgag
1801	cttgtaaatt	taggggattt	tgaaagtga	aatatatattg	gttcgccaaa	tgcaaaattc
1861	ttgcagcata	ttcaatcagc	aaattttggt	ttttctccag	cgcgaagggg	tatagtatcg
1921	tetaatcaca	atgtaatgaa	agatatctta	aattttgttg	gggattcggt	acacctacca
1981	agtgcagcgtg	ggtataatgc	aatgcaggtt	gctgctttgt	ttggtgacaa	agaagcagtg

NCBI Sequence Viewer v2.0

Page 3 of 3

```
2041 aaaatgcttg ctaaaagtgc taagccaagt gatcttaatt ttaagacttc agcaactcct
2101 actcogttaa atcttgcatg tcttagaggt gataatgagg tagtacgtgg gttagtaggt
2161 caacatggta ttgacattaa ccaacgtatg ggaagtgata aaaacactgt attgcattat
2221 gcaatcagca aaggagatag ttttcttggt caaaagatat tagctcatatc tggagttgat
2281 gttaattgtg agaataacct aggtcaaacg cctttacatt tagcagttga gggaggagat
2341 cctaagatag tatcttctct tcttaaagct ggtgcagtag ttaatcgtct ggatgataat
2401 ggtagatctg tactttcttc tgcgatagtt ccaggtagaa aagaaaaggg agtgctgggt
2461 atagttaata aattgctgga tagaggtgca gatattaatt tagatggaga ccacaatata
2521 ctttttgatc agtgtctaag ggtggatat aataatgtat tagataagtt aatacaacaa
2581 ggggttgaag ttaatcgaaa tagtgaaata cgtccaatgg tttatgctgc aatatctggt
2641 aatgagcatg ctatcaaata attagctaata gctgggtggag atgttaatga agtagtaaat
2701 aatccatcta gtaggcattc aggaaatcct ttaattatgg ttgcagtagc agatggtaat
2761 gcaggctctc ttaaaacatt agtttctgaa ggatgtgatg ttggtaaatc tggaaaagat
2821 ggttaatacag cgttacatta tgctgttagt cattcagata aagagtttgg taataaagct
2881 ataaagatat taatttcacg taatagtgtt gggactaata gagatattct tactcaaaag
2941 aataacgcag gtgatacacc tttacatgaa gctcttaagt caggtaatat taattctgta
3001 cagaatatct taagtgtgtg acatccaaga tacgcaaagg agatattaac agccagagac
3061 aaagaagggt acacaccaat gcattatact gttggagtaa ataattgtga tgttggtaga
3121 agtattctag agtctatgct ctctaaaggt gtgaataatc ttggagagat tgttgaggca
3181 caggatagta attttcgaac acctctgcat gctgctatta aaatatctga ttatcgtgct
3241 ggggacatga taataggtag cttatcgaaa acagaattgt caaagttatc gcaattaaac
3301 gatattaacg gggatacacc actacatctt tctgtcagt ctggtaatgt cgagatgaca
3361 caattcttct ttggaggttt ggataaacgt gaattaccta agacattaaa gatagcaaat
3421 aaaaatggag atactccttt acatgatgct ataagaaatg atgatattaa atctgcaaaa
3481 atgatgatta ggaattgtaa caaagaagaa cttgctaattg tattaaaatg taaagatagt
3541 tttggtaata cagtattgca tactattgct gaccaagtta ttgcaaatcc agaatacaaa
3601 aaagaccttg atggtttgat gaatttagca gtgaaaaggc taaagaatca agatctgaaa
3661 gatctagtta atacgcgaaa taactctgac gatactgttg cacattgtgc tcttttatcg
3721 gatatgaaat atgctcaaaa gatacttaaa tcatgtaacc atgatacatt agtgagagga
3781 aatagtaata atcaatcttt atcagagtgt attcgtgatg atagtaata taaaaaagg
3841 ggaattttta gtaagtcttt attttcaaaa ttaaagaaac ttgaggcacg agctgccagc
3901 gctagttatg aagaattatc tagtatcagt agtggtagtg atgtttcttc tgtatcaaca
3961 aatagcacag aagtaagtgc agtacctgaa gtggcaagaa gtagtggtgc tgtgtcgttc
4021 aaacatgtgc aagaaacagg agttgacacg tctggtcctt ctgatataga aagtttagag
4081 agattatctg atactagtct tgggtcaaat gattttgatc agcgaatggc agatttagat
4141 caagaaatag caaatattgt tagtggttta ccagaagtta cccaggtagc tgtaagtcaa
4201 caacaagcag catctcctag ttcagggtcaa gctgctgggtg tgcaacaaaa agagatgcag
4261 agataa
```

//

[Disclaimer](#) | [Write to the Help Desk](#)
NCBI | NLM | NIH

Feb 1 2006 13:21:03